REMARKS

Applicants have carefully reviewed the Office Action dated June 30, 2003. Claims 1-9, 11-15, 21, and 24-31 were rejected and remain pending.

The Examiner continues to reject the claims under 35 U.S.C. 35 §102(e) as being anticipated by Heck, U.S. Patent No. 6,083,207. The rejection is based on the assertion of the Examiner that the Heck patent discloses a hemostasis valve that compresses a device as that device is being passed through the hemostasis valve body. Applicants continue to traverse this rejection on multiple grounds.

First, the dilator, catheter or other medical device is not compressible in the Heck hemostasis valve and compression is not required for the valve to create a seal. Thus, the use of compression of a compressible valve sleeve to prevent flow through the valve distinguishes the current claimed invention from Heck. A second issue is that the Examiner appears to be making an argument that the Heck valve inherently compresses the device (300) as it is passed through the valve body. Because compression of the device (300) is not necessarily true, Applicants assert that this is a flawed use of the doctrine of inherency. Third, several pending claims describe a valve seat, which is not disclosed in Heck. Therefore, not every element of these claims is disclosed in Heck. Finally, the compressible valve sleeve is distinct from the dilator, catheter or other medical device in Heck and would be recognized as such by one skilled in the art. Each of these arguments highlights a difference between the current invention and Heck.

As described in each independent claim, the valve in the current invention uses compression of a compressible valve sleeve in order to restrict the flow of bodily fluids through the valve. Independent claim 1 recites, "compressing said valve sleeve for restricting fluid

flow." Independent claims 3, 12, 15, 24 and 28 have similar language describing the mechanism for restriction of fluid flow. The Examiner has asserted that Heck anticipates these claims.

In response, Applicants continue to traverse the assertion that the Heck patent discloses a hemostasis valve that compresses the dilator (300). Such an assertion is contrary to the manner in which a hemostasis valve normally operates. Patent language must be read as those of ordinary skill in the art would interpret them. *See* M.P.E.P. §2111.01. As a general rule, "words in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning." *Toro Co. v White Consolidated Ind., Inc.*, 199 F.3d 1295, 1299 (Fed Cir. 1999). It must be determined "how a person of experience in the field of the invention would, upon reading the patent documents, understand the words used to define the invention." *Id.* Applicants respectfully assert that these legal concepts from M.P.E.P. §2111.01 and the cases cited therein were not followed, and the Examiner is misinterpreting Heck.

A standard hemostasis valve does not create a seal by compressing a device that is being passed through it. As evidence of this standard definition, Applicants offer descriptions from medical texts, the description given of a hemostasis valve in the Heck patent, and the definition of a hemostasis valve from the patents cited in Heck. All of these sources point to one conclusion: that a standard hemostasis valve does not create a seal by compressing that which is being passed through it. According to M.P.E.P. §2111.01 and *Toro*, as stated above, Heck must be read to use this standard definition unless Heck clearly indicates an alternate definition. Heck does not offer such an alternate definition, and must be read to be using the standard definition of a hemostasis valve.

The standard definition of a hemostasis valve is a valve that can accommodate a device being passed through the body of the valve. Fluid flow around the device is prevented while the device is in the valve body. In addition, fluid flow through the valve is prevented after the device is removed because the valve returns to a closed position when the device is removed from the valve body. The medical device is not pinched off in the valve body to create the seal. Instead, a flexible membrane that seals around the medical device creates the seal. Because a standard hemostasis valve seals around a device that is passed through the valve, any lumen in a device that is being passed through the valve can be kept open while the device is in the valve body. The valve is also designed to allow the device to be passed through the valve with relative ease so the operator can feel the progress of the device in the patient's body and manipulation of the device is not difficult. At the same time, the proximal end of the lumen of the device can be sealed to prevent flow through the lumen of the device itself. This standard definition of a hemostasis valve is reinforced by general literature in the field of the invention, by language in the Heck patent, and by language and Figures in the patents referred to in the Heck patent.

Hemostasis valves are defined in medical literature as valves through which a device could pass, and in the process, the hemostasis valve would form a seal around the device that is being passed through the valve. Examples of devices that can be passed through the body of the valve are a guide catheter or a suction thrombectomy catheter. *See Alternatives to Open Vascular Surgery*, p.184 (a copy of this reference is attached for the Examiner's convenience). The fact that guide catheters or suction thrombectomy catheters can be passed through a hemostasis valve shows that a hemostasis valve does not crush the device that is being passed through the valve. With such devices that have a lumen and are passed through a hemostasis valve, it is desirable to maintain the open lumen through the device. If the lumen were not kept

open, it would eliminate the usefulness of many of the devices that are passed through the valve. For example, a guide catheter must be kept open for another device to pass through it, and a suction thrombectomy catheter must be kept open in order to perform the suction procedure through the lumen. The above-cited source does not mention a seal being created by compressing a medical device that is passed through the valve. The seal that is created by a hemostasis valve is a seal around the device that is being passed through the valve, and the valve is not designed to compress any such device.

In addition, an important attribute of a hemostasis valve is that a device can be passed through the valve easily, allowing the clinician to feel the progress of the medical device through the valve and into the patient's vasculature. Therefore, the valve must be tight enough to seal around the device that is being passed through the valve, but not so tight as to impede the "operator's ability to safely position or manipulate the catheter." *See Cardiac Catheterization: Application to Diagnostic and Therapeutic Procedures*, p. 121 (a copy of this reference is attached for the Examiner's convenience). Because compressing a device would result in an overly tight fit between the valve and the device being passed through the valve, a hemostasis valve is not designed to compress a device that is being passed through the valve.

These sources show that a hemostasis valve is a valve that can accommodate a device being passed through it while sealing around, and not compressing, the device.

As shown in responses to prior Office Actions, the Heck specification and the references used in Heck reinforce this definition. There is ample language in Heck that reinforces this standard definition. In a response dated March 25, 2003, Applicants noted the following language in Heck:

> One method of preventing, or at least limiting, the flow of blood out of a sheath while a pacemaker lead is being introduced is for the physician to place his

> thumb over the exposed end of the sheath or to squeeze or pinch the exposed end of the sheath between his thumb and forefinger. However, neither of these methods for reducing the undesired flow of blood and air through the sheath is desirable, because the opportunity for loss of blood and introduction of air is still present. In addition, the structure of these sheaths still requires the surgeon to hold onto it while it is in place in the vessel, thereby limiting the surgeon's ability to perform other medical procedures at the same time. Moreover, squeezing the exposed end of the sheath can deform or even break the sheath, making lead insertion difficult and increasing the likelihood of damage to the lead as it passes through the sheath. Further, even when holding the end of the sheath or pinching the sheath, flow of blood out of the sheath is not entirely stopped.

Column 2, lines 14-32 (emphasis added). As Applicants noted, the underlined portions of this quotation indicate that a device being passed through the valve should not be compressed or squeezed. This reinforces the accepted definition of a hemostasis valve; a hemostasis valve forms a seal around the device and does not form a seal by compressing the device. In addition, the following language was quoted from Heck:

> In addition, by sloping inward toward the lip (56), the inwardly sloped portion (60) of the outside wall (58) provides space for the lips (56) to separate without excessive force being applied, as the medical device passes through the lips (56). The inwardly sloped portion (60) of the outside wall (58) preferably slopes at an angle of about 35 to about 75 degrees from the position of the upper portion (62) so that it places pressure on the lip (56) to hold it closed against the corresponding lip of the cooperating hemostasis valve section (40), even when the medical device is forced between the lips (56).

Column 6, lines 43-53 (emphasis added). Again, instead of an indication that the medical device is to be compressed, Heck has stated that the hemostasis valve is provided with a structure specifically designed to protect the medical device against compression. The first underlined portion indicates that the hemostasis valve described by Heck is provided with a structure to reduce the compression on a medical device. The second underlined portion indicates that a medical device is advanced through the valve lips (56), and does not provide any indication of compression of the medical device. Further, this description of the operation of a hemostasis valve gives additional indications that a hemostasis valve is not intended to compress the device.

Specifically, if a hemostasis valve were meant to compress the device, it would be difficult to pass the device through the valve, as the valve would be continuously compressing the device as it passed through the body of the valve. Forcing the device through the valve in such a manner would not allow the operator to "feel" the device as it is navigated through the patient's body. This would be contrary to the description of a hemostasis valve given earlier in the *Cardiac Catheterization* source, where one of the purposes of a hemostasis valve is to place minimal pressure on the device so the operator can "feel" the progress of the device.

A third passage from Heck that was previously cited was:

> Each section (38, 40) of the partitioned hemostasis valve (14) is formed from a conventional hemostasis valve material, such as a pliant, resilient rubber, such as silicon rubber, latex rubber or a foamed rubber of 20 to 60 durometer, which can be shaped to fit within the respective body sections (26, 28) of the partitioned hemostasis valve housing (12).

Column 5, lines 53-59. A hemostasis valve "is formed from a conventional hemostasis valve material," which is soft and can conform around any device that is passed through the valve. This is further reinforcement that the accepted definition of a hemostasis valve is a valve that does not compress a device that is being passed through the valve.

All of these passages from Heck further reinforce that a hemostasis valve is a valve that can accommodate a device being passed through it while sealing around, and not compressing, the device.

As Applicants indicated in prior communications with the Examiner, the prior art cited in Heck also shows that a hemostasis valve does not seal by compressing a device that is passed through the body of the valve. Heck cites several patents that describe conventional hemostasis valves, including U.S. Patent Nos. 5,092,857 (hereinafter Patent '857) and 4,909,798 (hereinafter Patent '798). *See* Heck, column 1, lines 25-29. Both of these patents describe a hemostasis

valve as sealing around any devices that are passed through the valve, and neither patent mentions compressing the device that is passed through the valve body. *See* column 1, lines 37-40 of the '857 patent and column 1, lines 28-32 of the '798 patent.

Also, both the '857 patent and the '798 patent reference a body of patents that further explain the operation of a conventional hemostasis valve. Specifically, U.S. Patent Nos. 4,000,739 (hereinafter Patent '739), 4,655,752 (hereinafter Patent '752), 4,436,519 (hereinafter Patent '519), 4,610,665 (hereinafter Patent '665) and 4,673,393 (hereinafter Patent '393), and German Patent No. 30 42 229 were referenced in both the '857 patent and the '798 patent. According to the '857 patent and the '798 patent, these patents show examples of different designs of conventional hemostasis valves. *See* column 1, line 41 through column 2, line 41 of Patent '857 and column 1, line 41 through column 2, line 47 of Patent '798.

In the '739 patent, the gasket (22) sealingly engages with the catheter (46) that is passed through the valve, and it can be seen from the figures that the catheter (46) is not compressed. *See* column 2, lines 55-57 and Figure 2. "The slit (28) of the gasket (24) opens to allow passage of the catheter." *See* column 3, Lines 49-50. If the valve were meant to compress the catheter, it would not open to allow passage. In addition, "the annular gasket (22) forms a seal around the exterior of the catheter (46), thereby preventing any blood loss through the entrance hole (16)." Column 3, lines 51-53. The description of the invention mentions nothing about creating the seal by compressing the device. "The gasket (24) yields easily to the catheter and does not inhibit manipulation." Column 3, lines 53-55. This reinforces the fact that the catheter is not to be compressed. The hemostasis valve described in the '739 patent also maintains an open lumen in the catheter (46) in order to inject radiopaque material through the catheter while it is being advanced into the patient. *See* column 3, lines 58-60. All of this shows that the hemostasis valve

is a valve that can accommodate a device being passed through it while sealing around, and not compressing, the device.

In the '752 patent, the hemostasis valve (referred to as a cannula) essentially acts as a sheath for an instrument that is being passed through it. *See* column 4, lines 59-66. Further, it is stated that the cannula forms a seal "about an instrument" thereby preventing fluid from passing between the seal and the instrument and escaping out the top end of the cannula. Thus, the seal is not formed by compressing the instrument. *See* column 4, lines 41-58 and column 5, lines 4-5. It is also stated that the instrument can easily pass through the cannula, which would imply that the instrument should not be compressed. *See* column 2, lines 49-52. Most importantly, Figure 6 shows a device (100) being passed through the valve and the device (100) is not being compressed.

The '519 patent has a similar drawing that shows a device being passed through the valve body without the device being compressed. *See* Figure 2. Further, the specification of the '519 patent states that fluids can be passed through the device (here, a catheter). *See* column 3, lines 5-6. If the device were compressed, passage of fluid through the device would be restricted or completely occluded, as the Examiner has suggested. This would then defeat the purpose of the catheter. There are also references in the specification to the valve forming a seal around the catheter or device, and that the valve materials are soft, indicating further that compression is not the mode of sealing used by a hemostasis valve. *See* column 3, lines 58-60 and column 4, lines 7-10.

The '665 patent has four figures that show a device being passed through the valve, and none of these figures exhibit a device that is being compressed. *See* Figures 1, 3, 7 and 21. The valve opens to conform around the catheter when the catheter is placed through the valve, and

forms a seal around the catheter. *See* Figure 1, 3, 7 and 21, and column 5, line 53 through column 6, line 9. In addition, the seal material is described as a soft and pliable material and the seal is described as being formed between the outside surface of the catheter and the seal. Column 5, line 68 through column 6, line 9.

The '393 patent has four figures that show a device being passed through a valve, and the device is not being compressed in any of them. *See* Figures 1, 3, 11 and 15. Like the '665 patent, this valve opens to allow passage of the catheter, and the valve forms a seal around the catheter between the outside surface of the catheter and the seal. *See* column 4, line 28 through column 5, line 21.

Finally, German Patent 30 42 229 also has a figure in it that shows a device passing through the valve, and the device is not being compressed. *See* Figure 1 (a copy of the German patent is attached to this Response).

Again, both the '857 patent and the '798 patent cite the above-mentioned patents as references that describe standard hemostasis valves. *See* column 1, line 41 through column 2, line 41 of the '857 patent and column 1, line 41 through column 2, line 47 of the '798 patent. None of these references mention the compression of a device that is being passed through the valve. In fact, all of the references either show and/or imply the opposite, in that the hemostasis valve forms a seal around the device as the device is being passed through the valve body and does not compress the device. Thus, both the text and the drawings of the cited patents show that the hemostasis valve does not compress a device that is being passed through the valve body.

In summary, Applicants respectfully assert that Heck does not disclose a valve that compresses "said valve sleeve for restricting fluid flow." *See* language of claim 1 from the current invention. The standard definition of a hemostasis valve is established in the medical

literature, in the Heck patent, and in the references that are cited in Heck. That standard definition is a valve that can accommodate a device being passed through it while sealing around, and not compressing, the device. As mentioned earlier, M.P.E.P. §2111.01 and *Toro* state that the standard definition for a word should be used unless the body of the patent clearly states otherwise. Because Heck reinforces the standard definition and does not contradict it, M.P.E.P. §2111.01 and *Toro* demand that the standard definition be used. Thus, the hemostasis valve in Heck is a standard hemostasis valve, which is defined as a valve that can accommodate a device being passed through it while sealing around, and not compressing, the device. It is respectfully asserted that Heck does not disclose a valve that compresses "said valve sleeve for restricting fluid flow." Because Heck does not include all of the elements of the independent claims, it is respectfully asserted that all of the independent claims are allowable. Because all of the independent claims are now allowable, all of the dependent claims are also allowable for the same reasons and because they recite further distinct elements.

The Examiner has also stated that it must be true that the hemostasis valve of Heck compresses the dilator (300). *See* page 7 of the June 30, 2003 Office Action. It appears as though the Examiner is making an inherency argument, since an inherent characteristic is a characteristic that must be true. *See* M.P.E.P. §2112. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and it would be so recognized by persons of ordinary skill." M.P.E.P. §2112, citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Thus, in the case of the Heck patent, it must necessarily be true that the device (300) is compressed in the valve body. However, the evidence presented above leads to the conclusion that the opposite is true, that a hemostasis valve in general, and specifically the hemostasis valve

in Heck, is a valve that can accommodate a device being passed through it while sealing around, and not compressing, the device. Thus, it is not inherent that a hemostasis valve, including the hemostasis valve in Heck, compresses a device that is being passed through the valve body. Because a hemostasis valve does not inherently or otherwise compress a device that is passed through the body of the valve, and Heck uses this standard definition, Heck does not disclose a valve that compresses "said valve sleeve for restricting fluid flow."

It is respectfully asserted that, according to the legal doctrine from *In re Robertson* and M.P.E.P. §2112, compression of a compressible valve sleeve is not inherent in Heck. Thus, all of the elements of the current independent claims, and the claims depend therefrom, are not disclosed by Heck, and all claims should be allowable.

Applicants also respectfully traverse the Examiner's assertion that the compressible valve sleeve is disclosed in Heck. The Examiner has stated that the dilator, catheter or other medical device (300) is the equivalent of the compressible valve sleeve.

However, as Applicants have indicated in past Office Actions, the compressible valve sleeve is distinct from the dilator, catheter or other medical device that is referred to in Heck. The claim language "must be given [its] plain meaning unless applicant has provided a clear definition in the specification." M.P.E.P. §2111.01. "Words in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning." M.P.E.P. §2111.01, citing *In re Sneed*, 710 F.2d 1544, 218 USPQ 385 (Fed. Cir. 1983).

To state that a "compressible valve sleeve" in the claims of the current invention is the equivalent of a medical device that is referred to in Heck would give the phrase "compressible hemostasis valve" a meaning other than the meaning attributed to the phrase by one skilled in the

art. Specifically, one skilled in the art would not compress a medical device such as a dilator or a catheter. These medical devices do not operate well if kinks or bends are put in them, because it will affect their pushability through the vasculature and steerability through tortuous pathways. These devices are made to exacting standards that enable them to be effectively advanced through a body lumen, and one skilled in the art would not knowingly make these devices less effective by compressing them. One skilled in the art would not use a catheter for the compressible valve sleeve because the compression of the catheter would not allow for the operator to "feel" the progress of the catheter through the body lumen. In addition, the expense of a device such as a catheter or a dilator would prevent one of ordinary skill in the art from compressing such a device in the current invention when a compressible valve sleeve that is not a medical device would suffice. Finally, when a medical device with a lumen is used, it is desirable to keep the lumen open in order to maintain the functionality of the device.

Thus, for all of the above reasons, one skilled in the art would not use a medical device such as a catheter or dilator in place of the compressible valve sleeve. According to M.P.E.P. §2111.01 and *In re Sneed*, this definition must be used unless the patent clearly states an alternate definition. Because the current invention does not state an alternate definition, the definition that should be given a "compressible valve sleeve" should not be a medical device such as a dilator or a catheter. Because Heck does not disclose a compressible valve sleeve according to this definition and the phrase "compressible valve sleeve" is used in each independent claim, Heck does not anticipate the independent claims or the claims dependent therefrom, and all claims should be allowable.

Finally, Applicants respectfully assert that the rejection of claims 12, 27 and 31 is also improper for an additional reason. Specifically, a rejection based on 35 U.S.C. §102 must be

based on prior art that discloses all of the elements of the rejected claims. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. §2131, citing *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Independent claim 12 states, in part, that the valve body has a "seat for mating to said proximal valve sleeve distal region." In addition, dependent claims 27 and 31 have similar limitations that describe a valve sleeve seat that receives the distal end of the valve sleeve. The valve sleeve distal end abuts this valve sleeve seat (32), and thus the valve sleeve seat does not allow the compressible valve sleeve to be inserted into the tube (202) beyond the valve sleeve seat. *See* Specification at page 7, lines 8-9 and Figure 1. There is no such valve sleeve seat in the Heck disclosure. In fact, the dashed line in Figure 2 of Heck indicates that the device (300) can be inserted through the valve and into the tube (202). If there were a valve sleeve seat where the device (300) is designed to match up with the valve sleeve seat, the device (300) would not be able to extend through the valve body and into tube (202). In addition, Figure 1 of Heck shows the device (300) inserted in the hemostasis valve nearly up to the hub at the proximal end of the device (300). This means that the device (300) is extending through the valve and into the tube (202). Again, this would not be possible if the valve body contained a valve sleeve seat. Thus, Applicants respectfully assert that Heck does not disclose an element of claims 12, 27 and 31. According to M.P.E.P. §2131 and *Verdegaal*, this lack of disclosure of an element shows that Heck does not anticipate these claims, and they should be allowable.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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